EXHIBIT H

FBI Laboratory Quality Assurance Manual
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FBI Laboratory
Quality Assurance Manual

Introduction

Quality performance is the most important goal of the FBI Laboratory. As new and improved methods of forensic analysis are developed to meet the expanding needs of the criminal justice system, laboratory quality standards must progress in parallel. The FBI Laboratory is committed to diligently implementing policy and procedure changes to ensure quality in all facets of laboratory operations.

The FBI Laboratory quality system, represented by the Quality Assurance Manual and the Operations Manual, provides a mechanism for identifying and implementing the practices that support excellent performance. All units within the FBI Laboratory are responsible for the incorporation of quality practices and procedures consistent with the requirements of the quality system. All FBI Laboratory employees share responsibility for the overall success of the quality program by adhering to established quality measures.

The continued development and improvement of the FBI Laboratory quality system serves to increase confidence in the resulting work product while strengthening the professional integrity of the FBI Laboratory and its employees. Through the use of recognized quality practices and procedures, the FBI Laboratory will continue to meet the challenges of future laboratory missions.

D. Christian Hassell, Ph.D.
Assistant Director
FBI Laboratory Division

1 Scope

This Quality Assurance Manual contains or references the policies, practices, procedures, and forms of the Federal Bureau of Investigation Laboratory (FBI Laboratory) quality system that ensure technical competence and valid forensic examination and DNA database results. The FBI Laboratory Quality Assurance Manual (QAM) and the FBI Laboratory Operations Manual (LOM) facilitate meeting the American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB)-*International*® Accreditation Program requirements. The QAM and LOM do not apply to Terrorist Explosive Device Analytical Center (TEDAC) examinations.

ASCLD/LAB is an accrediting body for forensic science laboratories. The ASCLD/LAB-*International* Program requirements are based on the International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) International Standard 17025 General Requirements for the Competence of Testing and Calibration Laboratories (ISO 17025) and the American Society of Crime Laboratory Directors/Laboratory Accreditation Board-*International* Program Supplemental Requirements for the Accreditation of Forensic

Science Testing Laboratories. The combined requirements of ISO 17025 and ASCLD/LAB-*International* Supplemental Requirements are hereafter referred to as ASCLD/LAB-*International*. The QAM and LOM also facilitate internal and external audits of the quality system to evaluate the FBI Laboratory's conformance with ASCLD/LAB-*International*.

2 Terms and Definitions

See LOM - Definitions for the FBI Laboratory Quality Assurance Manual and FBI Laboratory Operations Manual.

3 Quality Initiatives

3.1 Forensic Examinations and Services

Forensic examinations of evidence are performed in the FBI Laboratory to support FBI and other federal, state, and local investigations as well as foreign investigations. The FBI Laboratory provides expert witness testimony on a national and international level. Additionally, FBI Laboratory personnel participate in ongoing field investigations by assisting with crime scene searches, providing DNA databasing services, as well as other scientific and/or technical services as necessary. The Handbook of Forensic Services contains a general listing of forensic services offered by the FBI Laboratory. Case acceptance policies for each caseworking unit are available on the FBI intranet.

3.2 Environmental Health and Safety

FBI Laboratory operations are performed in a safe manner and in accordance with the standards established by applicable regulatory agencies. The FBI Laboratory Safety Manual prepared by the FBI Laboratory Health and Safety Group is available on the FBI intranet.

3.3 Accreditation

The FBI Laboratory is accredited by the American Society of Crime Laboratory Directors/Laboratory Accreditation Board. The FBI Laboratory is committed to maintaining accreditation by ASCLD/LAB.

3.3.1 Obligations to ASCLD/LAB

As a condition of accreditation, the FBI Laboratory will inform ASCLD/LAB, within thirty calendar days, of significant changes relevant to its accreditation, in any aspect of status or operation relating to:

- Its legal or organizational status;
- The organization, top management, and key personnel;
- Main policies;

- Resources and premises;
- Scope of accreditation;
- Other such matters that may affect the ability of the FBI Laboratory to fulfill requirements for accreditation.

In addition, the FBI Laboratory obliges:

- A commitment to fulfill continually the requirements for accreditation within the FBI Laboratory's Scope of Accreditation, including an agreement to adapt to changes in the requirements in accordance with schedules adopted by ASCLD/LAB;
- To afford such accommodation and cooperation as is necessary to enable ASCLD/LAB to verify fulfillment of requirements for accreditation;
- To provide access to information, documents, and records as necessary for assessments and maintenance of accreditation;
- Where applicable, to provide access to documents or other information that provide insight into the level of independence and impartiality of the FBI Laboratory from any related body;
- To arrange the witnessing of the FBI Laboratory services when requested by the ASCLD/LAB;
- To claim accreditation only with respect to the scope for which the FBI Laboratory has been granted accreditation;
- To not use accreditation in such a manner as to bring ASCLD/LAB in disrepute;
- To pay fees as determined by ASCLD/LAB.

3.3.2 Disclosure of Noncompliance

The FBI Laboratory remains compliant with the standards of the ASCLD/LAB-*International* Program through each accreditation cycle. The FBI Laboratory submits an Annual Report to the ASCLD/LAB-*International* Program that includes a summary of any nonconforming work events and the actions taken, that have occurred since the last surveillance visit, and a summary of any other substantive Corrective Action Requests (see Nonconformity, Level 1) completed (or in process) since the last surveillance visit.

Further, the FBI Laboratory will disclose to ASCLD/LAB all substantive occurrences of noncompliance within thirty calendar days of determining that the noncompliance has occurred. The requirement to disclose is applicable to any requirement when the nonconformity fits the Nonconformity, Level 1definition. Disclosure of such occurrences will be in writing to the ASCLD/LAB Executive Director and will include a summary of the occurrence(s) and a statement of actions taken or being taken by the FBI Laboratory to:

- Determine the root cause of the problem;
- Determine who may have been impacted by the occurrence(s);
- Notify those who are potentially impacted by the occurrence(s), and;
- Appropriately correct and/or eliminate the cause of the occurrence(s).

3.4 Security and Access

It is the policy of the FBI Laboratory that all employees, evidence, DNA database samples, and case records are secure in the FBI Laboratory facility. Access to the FBI Laboratory building is restricted to FBI Laboratory personnel, non-FBI Laboratory employees as authorized by the Assistant Director (AD), and others when escorted by an FBI Laboratory employee. In the FBI Laboratory, the AD has delegated authorization responsibility to the Security Group. Security and access requirements are specified in the Security Reference Guide for Laboratory Division Personnel.

3.4.1 Due to the security classifications and the sensitivity of cases within the FBI Laboratory, the integrity of evidence must be of utmost importance. The AD of the FBI Laboratory does not allow any unauthorized individuals to have access to the laboratory areas for the purpose of viewing forensic examinations or DNA databasing.

When requests from unauthorized individuals are received, the Unit Chief of the individual receiving the request will advise the appropriate Section Chief. The Unit Chief or the Section Chief will consult the FBI Laboratory representative(s) from the Office of the General Counsel to address the request. If a deviation is granted, an electronic communication (EC) detailing the reason(s) for allowing deviation from this policy will be placed in the FBI Laboratory file.

4 Management Requirements

4.1 Organization

4.1.1 The Federal Bureau of Investigation (FBI) is the principal investigative arm of the United States Department of Justice. It has the authority and responsibility to investigate specific crimes assigned to it as well as matters where no prosecution is contemplated. [Title 28, United States Code, Section 533] The FBI also is authorized to provide other law enforcement agencies with cooperative services such as fingerprint identification, police training, and FBI Laboratory examinations. [Title 28, Code of Federal Regulations, Section 0.85]

The FBI is a field-oriented organization with the Headquarters (FBIHQ) located in Washington, District of Columbia. The executive managers within FBIHQ provide program direction and support services to field offices; satellite offices, known as resident agencies; specialized field installations; and foreign liaison posts. Although the FBI Laboratory is located at the FBI Academy complex in Quantico, Virginia, it is an entity within FBIHQ.

4.1.2 The FBI Laboratory provides forensic services to address a contributor's request for the examination of evidence and/or a request to confirm a DNA database match. These testing activities are conducted in such a way as to conform to the requirements of the ASCLD/LAB-*International* accreditation program.

4.1.3 The FBI Laboratory quality system covers forensic examinations and DNA databasing conducted at the FBI Laboratory in Quantico, Virginia and at any other location(s) where FBI Laboratory employees perform forensic services.

4.1.4 The FBI Laboratory Director is an AD in the FBI and reports directly to the FBI Executive AD for Science and Technology Branch. This ensures the independence of the FBI Laboratory from the rest of the organization. FBI Laboratory personnel encountering situations or conditions that could cause undue pressure and adversely affect the quality of the work will inform their Unit Chief and/or the Quality Manager.

4.1.4.1 The FBI Laboratory Director's responsibilities and authorities are defined in the Assistant Director's job description.

4.1.4.1.1 The FBI Laboratory Director has the authority to make and enforce decisions affecting the FBI Laboratory.

4.1.5 The FBI Laboratory:

a) Provides its personnel the authority and resources needed to carry out their duties including the implementation, maintenance, and improvement of the quality system. FBI Laboratory employees will identify departures from the quality system and initiate actions to prevent or minimize any conditions adversely affecting the quality system.

b) Has policies to ensure that all personnel are free from any undue pressures and influences that may negatively impact the quality of their work. [MAOP: Part I, , 1-13, Security Policy Manual, Corporate Policy Directives #0019D, #0188D, #0454D.] Additionally, all FBI Laboratory personnel annually review and sign the ASCLD/LAB Guiding Principles of Professional Responsibility for Crime Laboratories and Forensic Scientists.

c) Has policies and practices, including the LOM - Practices for Issuing a Report of Examination and the Practices for the Security of Evidence Storage Rooms, to protect contributors' confidential information. These policies and practices include guidance for protecting the electronic storage and transmission of FBI Laboratory *Reports of Examination* (7-1) as well as access to test data in examination areas. Additional policies and procedures are found in the Information Security Oversight Office Marking Guide, Security Reference Guide for Laboratory Division Personnel, and Security Policy Manual.

d) Has policies, as set forth in MAOP: Part I, 1-4 and Corporate Policy Directive #0019D, that provide guidance concerning any situations that could lessen confidence in the competence, impartiality, judgment or operational integrity of the FBI Laboratory.

e) Organizational Chart shows the organization's structure and the relationships between executive management, units, and support services. The FBI Laboratory's position in the FBI is shown in the FBI Organizational Chart.

f) Defines the responsibility and authority of all FBI Laboratory personnel in QAM - Section (4.2.6). Each FBI Laboratory employee will be accountable to only one immediate supervisor per each category of testing.
g) Technical management ensures examiners and technicians, including trainees, are adequately supervised. Employees responsible for supervising personnel are familiar with the purposes, methods and standard operating procedures conducted in their unit, and in the evaluation of corresponding results.
h) Technical management has overall responsibility for the technical operations and for providing the necessary resources to ensure the reliability and integrity of FBI Laboratory operations.
i) Quality Assurance and Training Unit (QATU) Chief serves as the FBI Laboratory Quality Manager and has direct access to the AD or his/her designee. He/She ensures that the quality system's effectiveness is continuously monitored.
j) Executive management has deputies as shown in the Organizational Chart.
k) Executive management ensures that FBI Laboratory personnel are aware of the relevance and importance of their activities and how they relate to the objectives of the quality system.

4.1.6 Top management communicates with FBI Laboratory personnel by email, meetings, Quality Assurance Working Group (QAWG) meetings, or other means concerning the effectiveness of the quality system.

4.1.7 The FBI Laboratory Health and Safety Group Program Manager (i.e., Industrial Hygienist and Safety Manager) has the responsibility and authority for ensuring that the health and safety program described in the FBI Laboratory Safety Manual is implemented and followed at all times.

4.1.8 Top management is defined in LOM - Definitions for the FBI Laboratory Quality Assurance Manual and FBI Laboratory Operations Manual. Key management is designated by a member of top management during his/her absence and by a Unit Chief during his/her absence.

4.2 Quality System

4.2.1 The FBI Laboratory is committed to its quality system as outlined in the QAM, LOM, unit quality and procedures manuals, forms, and training manuals. These documents are available on the FBI intranet. Additional quality system documents such as instrumentation manuals are available in the units.

4.2.2 Quality System Policy Statement

The management of the FBI Laboratory is dedicated to good laboratory practice and to the quality of the forensic services provided to contributors. The quality system of the FBI Laboratory ensures that functions are performed as intended and conform to the requirements of

ASCLD/LAB-*International*. FBI Laboratory employees are responsible for ensuring that they understand and apply the quality system to their daily activities.

With the support of the FBI Laboratory's management and input from personnel, new policies, practices and procedures are developed and implemented when necessary. All quality system documents are reviewed annually and updated as necessary to continuously improve the effectiveness of the quality system. If conditions or situations having an adverse impact on the quality system are identified, appropriate changes will be made and/or corrective actions will be implemented.

The FBI Laboratory quality system goals and objectives are as follows:

- To assure that FBI Laboratory results provided to contributors and caseworking laboratories are reliable and scientifically sound.
- To establish formal methods of quality assurance within the FBI Laboratory through the implementation of recognized standards for good laboratory practice.
- To assure procedures are valid, dependable, reproducible, and are adequate for the intended purpose.
- To ensure the routine operational performance of units within the FBI Laboratory are monitored.
- To ensure all areas of the quality system are periodically audited to demonstrate that policies, practices, and procedures are being followed and forms are being used.
- To maintain quality, excellence, and integrity.
- To conform to the requirements of ASCLD/LAB-*International*.
- To ensure necessary training is provided for personnel to carry out the provisions of the quality system.

4.2.2.1 The management of the FBI Laboratory is committed to the *ASCLD/LAB Guiding Principles of Professional Responsibility for Crime Laboratories and Forensic Scientists* (Appendix A).

4.2.2.2 Top management ensures the *ASCLD/LAB Guiding Principles of Professional Responsibility for Crime Laboratories and Forensic Scientists* are reviewed annually with FBI Laboratory personnel. A record of the review is maintained by each Unit Chief and/or Executive Management, as appropriate. This review may be conducted and documented during Performance Appraisal Reviews (PARs).

4.2.3 Top management is committed to the development, implementation, and continuous improvement of the quality system. This is communicated via policies, FBI Laboratory News emails, targeted issue emails, or meetings, including QAWG meetings, with FBI Laboratory personnel.

4.2.4 Top management advises FBI Laboratory personnel via policies, FBI Laboratory News emails, targeted issue emails or meetings, including QAWG meetings, of the importance of

addressing contributor requests and complying with any relevant statutory and regulatory requirements.

4.2.5 Document Hierarchy

The FBI Laboratory's quality system is comprised of the QAM, LOM, unit quality manuals and procedures, and forms. The authority to implement change within each category is described below.

FBI Laboratory policy is set forth in this QAM. It is approved by the AD of the FBI Laboratory and the Quality Manager. The Quality Manager issues this document. Any revisions to the QAM are approved by the AD and the Quality Manager.

FBI Laboratory practices and accompanying forms are found in the LOM. Practices are used to implement FBI Laboratory policies defined in the QAM. These practices are approved by the AD of the FBI Laboratory and the Quality Manager. The Quality Manager issues these practices. Any revisions to the LOM are approved by the AD and the Quality Manager.

Unit quality manuals and procedures as well as forms supplement the FBI Laboratory QAM and LOM. Unit quality manuals and procedures and revisions thereof are approved by the managing Unit Chief (UC) and the Quality Manager, as well as the Technical Leader, as appropriate. An individual(s) designated in a unit issues unit documents.

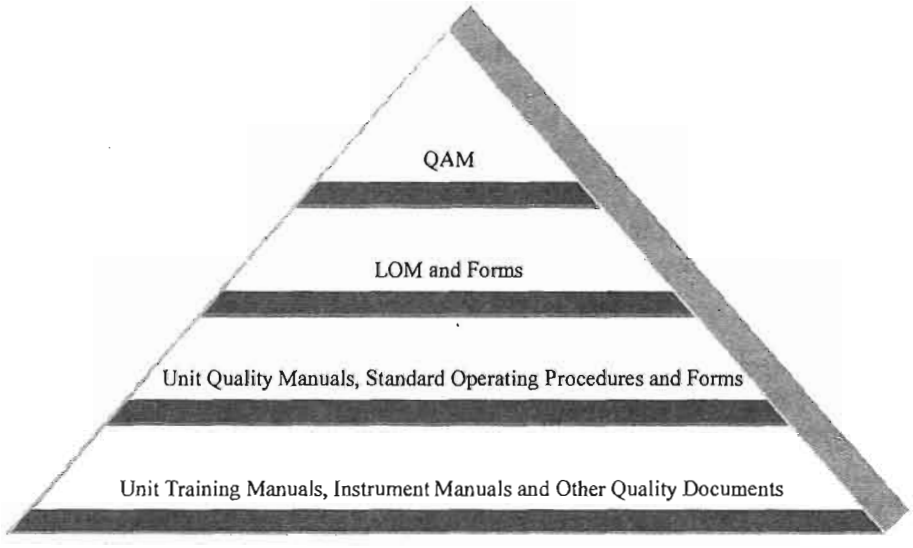


Figure 1: FBI Quality System Document Hierarchy

4.2.6 Authority and Responsibility for the Quality System

To be successful, the FBI Laboratory quality system has the complete support and commitment of all personnel. This section describes FBI Laboratory employees' responsibilities for implementing the quality system.

4.2.6.1 The Assistant Director and Deputy Assistant Director:

- Support and promote the quality system.
- Ensure conformance with ASCLD/LAB-*International*.
- Ensure that the policies, practices, procedures, and forms within the quality system are documented.
- Ensure that FBI Laboratory personnel understand and apply current policies and practices to appropriate situations.

4.2.6.2 Section Chiefs:

- Support and promote the quality system.
- Ensure conformance with ASCLD/LAB-*International*.
- Ensure that the current policies, practices, procedures, and forms are implemented within the section.
- Ensure that the corrective action is taken and documented to resolve deficiencies when they are found.

4.2.6.3 Unit Chiefs:

- Support and promote the quality system.
- Ensure conformance with ASCLD/LAB-*International*.
- Ensure that the unit-specific quality system is annually reviewed.
- Communicate the quality system to all employees within the unit.
- Appropriately delegate authority within the unit to implement the quality system; this authority may be delegated to a Technical Leader. If the Unit Chief has not been previously qualified as an Examiner in a discipline or category of testing within his/her unit, he/she will ensure an individual that has been qualified as an Examiner in that discipline or category of testing being affected or a Technical Leader is consulted when necessary. This includes, approval of technical procedures and corrective actions. Additionally, a Unit Chief will not conduct technical reviews on examination records and FBI Laboratory *Reports of Examination* (7-1) unless he/she is qualified in that discipline or category of testing.
- Ensure that all unit personnel receive necessary training and are qualified for their assigned work.
- Ensure approval for the selection and use of technical procedures within the unit; criteria establishment for technical procedure validation; and as necessary, review, and update technical procedures.
- Ensure the completeness of FBI Laboratory *Reports of Examination* (7-1) and supporting case records through technical and administrative reviews.

- Ensure that appropriate corrective actions are taken and documented to resolve deficiencies when they are found.

4.2.6.4 Supervisors:

- Support and promote the quality system.
- Ensure conformance with ASCLD/LAB-*International*.
- Communicate the quality system to employees within the unit.
- Appropriately delegate authority within the unit to implement the quality system.
- Ensure that unit personnel receive necessary training and are qualified for their assigned work.
- Ensure the completeness of FBI Laboratory *Reports of Examination* (7-1) and supporting case records through technical and administrative reviews.
- Ensure that appropriate corrective actions are taken and documented to resolve deficiencies when they are found.

4.2.6.5 The Quality Assurance and Training Unit Chief:

- Serves as the Quality Manager.
- Ensures conformance with ASCLD/LAB-*International*.
- Ensures all quality assurance programs function in accordance with FBI Laboratory goals and objectives.
- Ensure that the policies, practices, procedures, and forms within the quality system are documented.
- Advises management regarding the development, implementation, and maintenance of the quality system.
- Provides reports, as necessary, to the FBI Laboratory AD on the progress of quality assurance activities.
- Advises management on issues relating to the FBI Laboratory quality system and good laboratory practice.

4.2.6.6 Quality Assurance and Training Unit Personnel:

- Coordinate the development and revision of the quality system.
- Assist units, as needed, in the development of specific quality system documents.
- Conduct periodic quality system audits to provide management with the necessary verification that established quality system policies, practices, procedures, and objectives are being met.
- Provide guidance and direction to FBI Laboratory personnel regarding conformance with accreditation standards.

4.2.6.7 Quality Assurance Working Group Members:

- Are from appropriate units.
- Attend the QAWG meetings.
- Participate in discussions regarding the quality system.

- Participate in revising the QAM and LOM, as necessary.
- Provide assistance, as needed, in performing audits.

4.2.6.8 Examiners:

- Ensure compliance with current policies, practices, procedures, and forms.
- Ensure that unit procedures are performed in a careful and responsible manner in accordance with current policies and practices.
- Make recommendations and suggestions for improving the FBI Laboratory quality system as appropriate.
- Support technical management, when necessary, by reviewing validation records, technical procedures, and deviation requests and conducting technical and administrative reviews.

4.2.6.9 Technicians:

- Ensure compliance with current policies, practices, procedures, and forms.
- Ensure that unit procedures are performed in a careful and responsible manner in accordance with current policies and practices.
- Advise examiners of relevant case-related or DNA databasing issues.

4.2.6.10 Administrative Personnel:

- Perform administrative/clerical duties in a careful and responsible manner.
- Ensure compliance with current policies, practices, procedures, and forms.

4.2.7 Top management ensures proposed revisions to the FBI Laboratory quality system maintain the integrity of the system when changes are implemented.

4.3 Document Control

4.3.1 General

FBI Laboratory personnel manage the documents that comprise its quality system according to the LOM - Practices for Document Control. Controlled document distribution is accomplished by accessing the FBI intranet and/or by a unit creating a unit document distribution list, numbering the documents, and assigning them to specific individuals. The QAM, LOM, unit quality manuals and procedures, forms, and training manuals posted on the FBI intranet are the official versions of the documents. Hard copies of documents printed from the FBI intranet are uncontrolled. When a form is printed off the FBI Laboratory Division forms intranet site or a unit forms intranet site and it is completed electronically or printed blank to complete by hand, it will be considered a record.

4.3.2 Document Approval and Issue

4.3.2.1 Prior to implementation, all FBI Laboratory quality system documents are thoroughly reviewed, approved for release by authorized personnel, and made available for use by employees. The LOM - Practices for Document Control contains provisions for identifying the current revision of documents, for distributing quality system documents, and to preclude the use of invalid and/or obsolete documents.

4.3.2.2 The LOM - Practices for Document Control ensures that:

a) Current revisions of appropriate quality system documents, including procedures, externally produced quality documents, and instrumentation manuals are available where essential operations are performed;
b) Quality system documents are annually reviewed and revised as necessary to ensure they are suitable and comply with applicable requirements;
c) Invalid or obsolete documents are promptly removed;
d) Archived quality system documents are marked appropriately to preclude their use.

4.3.2.3 FBI Laboratory prepared quality system documents are uniquely identified according to the requirements of the LOM - Practices for Document Control.

4.3.3 Document Changes

4.3.3.1 Revisions to FBI Laboratory prepared quality system documents are subject to the same review, approval, documentation, and issuance requirements as the original document. Revisions to instrumentation manuals or externally produced quality documents are subject to the same review and approval as the original document. Additionally, appropriate personnel will have access to any information necessary to conduct the review and approve the revision. [LOM - Practices for Document Control]

4.3.3.2 Altered or new text is identified in the quality system documents according to the LOM - Practices for Document Control.

4.3.3.3 The FBI Laboratory quality system does not permit the amendment of documents by hand for internally prepared documents. Amendments by hand to externally prepared documents are performed according to LOM - Practices for Document Control.

4.3.3.4 The LOM - Practices for Document Control also applies to documents maintained in computerized systems.

4.4 Review of Requests, Tenders, and Contracts

4.4.1 The LOM - Practices for Processing a Request for Examination, the Practices for Case Assignment and the Handbook of Forensic Services provide guidance for the review of requests for examinations and the contract that is entered when a contributor submits evidence to the FBI

Laboratory. Additionally, the LOM - Practices for the Examination of Evidence details the requirements for unit personnel and examiners contacting the contributor prior to examinations commencing. These practices and handbook ensure that the:

- Request Coordinator (RC) prepares an *Examination Plan* (7-262) (See LOM - Practices for Case Assignment) to the extent possible, which documents the services that fulfill a contributor's request;
- FBI Laboratory is capable of conducting the requested examinations;
- Examiner selects an appropriate technical procedure, to the extent possible, that is dictated by the nature of the evidence and a contributor's request;
- Unanswered issues in the request are reconciled by the RC and/or the examiner prior to any work being performed.

4.4.2 The *Examination Plan* (7-262) documents the review of the incoming communication which details the request for examination(s). Any significant changes to the *Examination Plan* (7-262) are documented by the RC. In addition, a person from each unit identified on the *Examination Plan* (7-262) contacts the contributor upon receipt of the evidence in that unit according to the LOM - Practices for the Examination of Evidence. An *Activity and Communication Log* (7-245) (See LOM - Practices for the Examination of Evidence) is used to record discussions with a contributor relating to their request(s). The 7-262 and the 7-245 are included in the FBI Laboratory file. [LOM - Practices for Case Assignment]

4.4.3 Reviews of requests on any work that is subcontracted by the FBI Laboratory are conducted by the appropriate Unit Chief.

4.4.4 Any significant deviations from a contributor's request, such as conducting additional examinations that were not requested, are communicated to the contributor by the examiner initiating the change. This communication is recorded on the *Activity and Communication Log* (7-245).

4.4.5 Any changes to the *Examination Plan* (7-262) are communicated to all affected examiners by the Request Coordinator.

4.5 Subcontracting of Examinations

4.5.1 The FBI Laboratory selects competent subcontractors to conduct forensic examinations when necessary. FBI Laboratory Unit Chiefs or Technical Leaders are responsible for evaluating the competency of subcontractors. A subcontractor's competence can be demonstrated by their accreditation by ASCLD/LAB or by satisfactory results of an audit conducted by FBI Laboratory personnel. The appropriate Unit Chief or Technical Leader may also determine a subcontractor to be competent, on a case-by-case basis, if the subcontractor is accredited by another ISO 17025 accrediting body or by accepting the results of an independent audit.

4.5.2 When the FBI Laboratory subcontracts work, the appropriate Unit Chief or designee will advise the contributor of the arrangement in writing. This will be recorded in the FBI Laboratory file.

4.5.3 The appropriate Unit Chief is responsible for the quality of a subcontractor's work, unless the contributor, judge, or judicial order specifies the subcontractor.

4.5.4 FBI Laboratory Unit Chiefs are responsible for maintaining a list of all competent subcontractors who are approved for conducting forensic examinations. Records are maintained of the subcontractor's conformance with the requirements of ISO 17025 for the work in question.

4.5.5 The FBI Laboratory may assist a contributor by facilitating forensic examinations that the FBI Laboratory does not conduct. If the examination will be conducted by an external agency, the appropriate Unit Chief or designee will obtain approval from the contributor prior to the work commencing. The appropriate Unit Chief or designee will also ensure that the contributor is aware that the forensic examinations are outside the expertise of the FBI Laboratory and therefore the FBI Laboratory cannot technically review the work. This approval will be recorded in the FBI Laboratory file.

4.6 Purchasing Services and Supplies

4.6.1 Federal and FBI Finance Division Procurement Policies and Regulations govern the procurement of products and services from sources external to the FBI. The Planning and Budget Unit (PBU) is responsible for the planning, budgeting, and acquisition/contracting of services and supplies for the FBI Laboratory. PBU ensures compliance with all Federal, bureau, and divisional budget/accounting policies. Units have procedures for the reception and storage of reagents and consumable materials necessary for forensic examinations.

4.6.2 FBI Laboratory units evaluate quality affecting supplies, reagents, and consumables purchased by the FBI Laboratory to ensure that they comply with specifications defined in the appropriate standard operating procedure (SOP) and/or purchase request. These materials are not used until their compliance is verified. Units maintain records of steps taken to check conformance of these materials.

4.6.3 FBI Laboratory units ensure that purchase requests contain information describing the supplies and services ordered, if they affect the quality of examinations or DNA databasing. These requests are reviewed and approved for technical content by the Unit Chief or designee prior to ordering.

4.6.4 FBI Laboratory units evaluate suppliers of critical consumables, supplies, and services and maintain records of these evaluations. Units maintain a list identifying approved suppliers.

4.7 Service to the Contributor

4.7.1 The LOM - Practices for the Examination of Evidence details the requirements for unit personnel and examiners contacting the contributor prior to examinations commencing. [QAM – Section 4.4.2] Additionally, FBI Laboratory employees communicate with contributors as needed to answer any questions concerning the status of the requests.

4.7.2 The FBI Laboratory encourages feedback from its contributors according to the LOM - Practices for Customer Satisfaction Assessment of FBI Laboratory Services.

4.8 Complaints

As part of the FBI Laboratory's commitment to provide reliable forensic examinations, employees take appropriate steps to address valid complaints regarding their services. Any employee receiving a complaint notifies their Unit Chief. Unit Chiefs are responsible for investigating a complaint and ensuring that Technical Management is made aware of the complaint, if appropriate. When necessary, the FBI Laboratory addresses complaints by implementing the LOM - Practices for Corrective Action. Records are maintained by the affected Unit Chief of all complaints, any relevant investigations and responses by the affected unit. Records of corrective actions implemented by FBI Laboratory personnel are maintained by QATU.

4.8.1 FBI Laboratory employee complaints concerning the quality system are also governed by this policy and the LOM - Practices for Corrective Action.

4.9 Control of Nonconforming Testing

4.9.1 The QAM - Section (4.11), QAM - Section (3.3.2), and the LOM - Practices for Corrective Action are followed when a nonconformity occurs during the examination or DNA databasing process. These policies and practice:

a) Designate the actions to be taken and the individual responsible for managing the nonconformity;
b) Provide guidance to determine the level of the nonconformity (Level 1 or Level 2);
c) Ensure that corrective actions are implemented in a timely manner and the acceptability of the nonconformity will be evaluated;
d) Ensure that, when necessary, the contributor or caseworking laboratory is notified and results of the examination or DNA databasing are amended;
e) Define the responsibility for authorizing the resumption of work.

There are times when deviating from the QAM, LOM, unit quality manuals and procedures, and/or forms are necessary. It is the policy of the FBI Laboratory that deviations are reviewed and authorized to ensure that quality is not compromised. The LOM - Practices for Authorizing Deviations specifies the requirements for requesting and approving deviations.

4.9.2 Where the evaluation indicates that the nonconformity could recur or if there is a question that FBI Laboratory personnel are complying with the QAM, LOM, unit quality manuals and procedures, or forms, QAM - Section (4.11) and the LOM - Practices for Corrective Action are promptly followed.

4.10 Improvement

The FBI Laboratory uses quality system documents, objectives, audit results, data analysis, corrective actions, preventive actions, and management reviews to continuously improve the effectiveness of the quality system.

4.11 Corrective Action

4.11.1 General

Corrective actions in the FBI Laboratory are identified as Corrective Actions or Follow-Up Actions. Any FBI Laboratory employee may identify conditions or situations where corrective actions are required. A Corrective Action Request (7-254) is initiated for a Level 1 nonconformity while a Follow-Up Action Request (7-255) is implemented for a Level 2 nonconformity in accordance with the LOM - Practices for Corrective Action. The intent of a corrective action is to prevent the recurrence of the nonconformity that affects the quality of work performed or the integrity of the evidence within the FBI Laboratory. It is important that corrective actions are initiated in a timely manner to minimize the impact of the nonconformity.

4.11.2 Root Cause Analysis

The LOM - Practices for Corrective Action includes initiating an investigation to determine the root cause(s) of the nonconformity.

4.11.3 Selection and Implementation of Corrective Actions

The LOM - Practices for Corrective Action provides guidance for determining the level of the nonconformity (Level 1 or Level 2). Once the level is determined, the appropriate personnel select, document, and implement the action(s) most likely to eliminate the nonconformity and to prevent recurrence. Corrective actions are appropriate to the magnitude and risk of the nonconformity.

4.11.4 Monitoring and Verification of Corrective Actions

The QATU monitors and verifies the results of corrective actions to ensure that they have been effectively resolved. [LOM - Practices for Corrective Action]

4.11.5 Additional Audits

Where conditions or situations require a corrective action, the Quality Manager determines if an additional audit is necessary to assess the effectiveness of the corrective action. If an audit is required, the audit is conducted in a timely manner. [LOM - Practices for Corrective Action]

4.12 Preventive Action

4.12.1 Preventive actions are taken to prevent occurrence whereas corrective actions are taken to prevent recurrence. FBI Laboratory personnel, either independently or as part of an audit, may

identify needed improvements, opportunities for improvement, and potential sources of nonconformity. If a preventive action is warranted, the LOM - Practices for Preventive Action is followed.

4.12.2 The LOM - Practices for Preventive Action includes measures for verifying the effectiveness of any preventive actions that are implemented.

4.13 Control of Records

4.13.1 General

4.13.1.1 The FBI Laboratory and the Records Management Division (RMD) have policies and practices for the identification, collection, organization, accessibility, filing, storage, maintenance, and disposal of quality records and technical records. [LOM - Practices for Retaining Case-Related Records] Quality records include items such as internal audit reports, management reviews, corrective action forms, and preventive action forms. Quality records are maintained by the appropriate unit according to RMD and/or FBI policy, or at least for the current ASCLD/LAB-*International* Accreditation cycle and the previous ASCLD/LAB-*International* Accreditation cycle unless otherwise stated.

4.13.1.2 All FBI Laboratory records are legible and readily retrievable from storage in appropriate FBI facilities. Retention times for records are based on RMD and/or FBI policy and/or ASCLD/LAB-*International* requirements.

4.13.1.3 Access to FBI Laboratory files is controlled according to FBI and RMD policies.

4.13.1.4 Electronic records on the Sentinel and FBINET systems are maintained by the Information Technology Services Division (ITSD). Access to these records is controlled. Units have procedures for backing up records stored electronically on other controlled media that are not located on the FBINET systems.

4.13.2 Technical Records

4.13.2.1 The FBI Laboratory retains case records sufficient to establish an audit trail for a defined period in accordance with RMD requirements. Calibration records, staff records, and a copy of the *Report of Examination* (7-1) are also retained for a defined period in accordance with QAM – Section (4.13.1.2). These records contain adequate information to facilitate, if possible, the identification of factors affecting uncertainty and to enable the examination to be repeated under conditions similar to that of the original examination. [LOM - Practices for Instrument Calibration and Maintenance and Practices for Retaining Case-Related Records] Personnel responsible for the examination of evidence, the technical reviewer, and the administrative reviewer are identified in the FBI Laboratory file. [LOM - Practices for the Examination of Evidence and Practices for Reviewing a Report of Examination]

4.13.2.2 Case notes include observations, data, and calculations. These notes are recorded contemporaneously with, and identifiable to, the specific examination performed. [LOM - Practices for the Examination of Evidence]

4.13.2.2.1 Examination records reflect, at a minimum, the starting and ending dates of the examinations as well as the requirements detailed in the LOM - Practices for the Examination of Evidence.

4.13.2.3 Mistakes that occur in case records are corrected with an initialed single strike-out and the correction entered alongside. Nothing in the case records is erased or otherwise made illegible. In the case of electronically stored records, equivalent measures are taken to avoid loss or change of original data. [LOM - Practices for the Examination of Evidence]

4.13.2.3.1 Any change made to existing hardcopy case records is initialed by the person making the change. [LOM - Practices for the Examination of Evidence]

4.13.2.3.2 Any change made to completed examination records generated and/or maintained electronically is tracked. Examination records are considered complete prior to any technical or administrative review.

4.13.2.4 The LOM - Practices for Retaining Case-Related Records, the Practices for the Examination of Evidence and the caseworking unit quality manuals identify what records are maintained in the FBI Laboratory file.

4.13.2.5 Examination records are such that, in the absence of the examiner, another qualified examiner could evaluate the examinations performed and interpret the data. [LOM - Practices for the Examination of Evidence and Practices for Reviewing a Report of Examination]

4.13.2.5.1 Examination records in the latent print discipline meet the criteria as described in Appendix C of ASCLD/LAB-*International*, in addition to the applicable record requirements described in section 4.13.

4.13.2.5.2 Instrumental analyses operating parameters are recorded in Standard Operating Procedures (SOPs), instrument logbooks and/or examination records.

4.13.2.6 The FBI Laboratory number and the examiner's handwritten initials (or secure electronic equivalent of initials or signature) are on each page of the examination records. [LOM - Practices for the Examination of Evidence]

4.13.2.7 When examination records are prepared by a technician, the technician's handwritten initials (or secure electronic equivalent of initials or signature) are on each page of the examination records representing his/her work. [LOM - Practices for the Examination of Evidence]

4.13.2.8 The FBI Laboratory number is on each page of the administrative records [LOM - Practices for the Examination of Evidence].

4.13.2.9 The FBI Laboratory number for each case for which data is generated is appropriately recorded on the printout when data from multiple cases is recorded on a single printout. [LOM - Practices for the Examination of Evidence]

4.13.2.10 When information is recorded on the front and back of an examination record, each side is identified as an individual page and initialed and labeled with the FBI Laboratory number according to the LOM - Practices for the Examination of Evidence.

4.13.2.11 Case records are documented in ink and are of a permanent nature. Any exceptions to this are noted in the LOM - Practices for the Examination of Evidence.

4.13.2.12 All identifications and associations are confirmed by another appropriately qualified examiner. If there is not a qualified person within the FBI Laboratory to confirm an identification or association for the category of testing being reviewed, a major deviation will be requested in accordance with the LOM - Practices for Authorizing Deviations. This confirmation is documented according to the LOM - Practices for Reviewing a Report of Examination.

4.13.2.13 Abbreviations and notations specific to the unit are acceptable if they are clearly defined by the unit. FBI Laboratory units maintain a list of unit specific abbreviations and/or symbols in the unit quality manual that are used by their personnel. [LOM - Practices for the Examination of Evidence]

4.14 Internal Audits

4.14.1 The LOM - Practices for Internal Audits are followed when conducting scheduled audits to verify that operations conform to the requirements of the FBI Laboratory quality system and ASCLD/LAB-*International*. Audits are performed to measure and evaluate the effectiveness of the quality system, to verify the effectiveness of corrective actions, and to recommend improvements for FBI Laboratory operations. The Quality Manager ensures that audits are planned and organized as required and as requested by executive management. Such audits are carried out by trained auditors of the QATU and/or other trained FBI Laboratory individuals as defined in LOM - Definitions for the FBI Laboratory Quality Assurance Manual and FBI Laboratory Operations Manual. Records of auditor training are maintained by the QATU.

4.14.1.1 Internal audits are conducted, at a minimum, on an annual basis according to the LOM - Practices for Internal Audits.

4.14.1.2 Internal audit records are maintained by Audit Program Manager according to RMD and/or FBI policy, or at least for the current ASCLD/LAB-*International* Accreditation cycle and the previous ASCLD/LAB-*International* Accreditation cycle unless otherwise stated.

4.14.2 When an audit identifies a nonconformity, the Audit Program Manager will address the nonconformity according to the LOM - Practices for Internal Audits. When necessary, the FBI Laboratory will notify contributors or caseworking laboratories, in writing, if FBI Laboratory results have been affected.

4.14.3 An audit report is issued for every internal audit according to the LOM - Practices for Internal Audits.

4.14.4 The effectiveness of a corrective action resulting from an audit finding is verified [LOM - Practices for Corrective Action] and written notification provided to the appropriate unit when the nonconformities have been adequately remediated. [LOM - Practices for Internal Audits]

4.14.5 The FBI Laboratory submits an Annual Report to ASCLD/LAB within 30 days following its accreditation anniversary date.

4.15 Management Reviews

4.15.1 In conjunction with the Quality Manager, the FBI Laboratory's executive management evaluates the quality system and examination/DNA databasing activities to ensure their continued suitability and effectiveness. This management review is used as the foundation for future development of FBI Laboratory goals and objectives as well as any necessary changes or improvements to the quality system. The management review is conducted no more than 30 days prior to the accreditation anniversary date or no more than 30 days after the anniversary date.

This review assesses:

- The suitability, adequacy, and completeness of FBI Laboratory quality system documents for meeting the quality objectives of the FBI Laboratory and the standards of the ASCLD/LAB-*International*;
- Any reports from technical management;
- The internal audit program;
- Any preventive, follow-up, and/or corrective actions;
- Any external assessments;
- The proficiency test program;
- Changes in the volume and type of work being performed in the FBI Laboratory;
- Any feedback or complaints from contributors and FBI Laboratory personnel;
- Any recommendations for improvement;
- The adequacy of the organizational structure, staff training, and resources to implement the FBI Laboratory quality system.

4.15.1.1 Management reviews are conducted at least once per calendar year.

4.15.1.2 Management reviews are documented by an electronic communication (EC) and the records are retained by the Quality Manager for at least one ASCLD/LAB-*International* accreditation cycle or five years, whichever is longer.

4.15.2 Any issues identified and actions taken to address them through the management review process will be appropriately documented. Top management will ensure the actions are carried out within an appropriate and agreed upon timescale.

5 Technical Requirements

5.1 General

5.1.1 The FBI Laboratory ensures correct and reliable forensic examinations and DNA databasing by using adequately trained personnel, appropriate facilities, validated standard operating procedures, properly maintained and calibrated equipment and instrumentation, and by maintaining the integrity of evidence and DNA database samples. When applicable, traceable reference standards and materials and suitable sampling procedures are utilized.

5.1.2 The FBI Laboratory considers the factors cited in QAM - Section (5.1.1) when developing and validating standard operating procedures, in the training and qualification of personnel, and in the calibration and maintenance of the equipment it uses.

5.1.3 FBI Laboratory units have procedures for routinely checking the reliability of their reagents.

5.1.3.1 Reagents prepared in the FBI Laboratory are labeled with, at a minimum, the identity of the reagent and the date of preparation or lot number. Records maintained by the units identify who made the reagent, the date of preparation or lot number, who tested it and whether it worked as expected. The reliability testing occurs before use or, if appropriate, concurrent with the test. Unit specific procedures and the FBI Laboratory Safety Manual may establish additional requirements regarding the preparation, storage, and labeling of reagents.

5.2 Personnel

5.2.1 Technical management ensures that only qualified technical personnel operate specific equipment, conduct forensic examinations and DNA databasing, confirm identifications and associations, review results, and issue *Reports of Examination* (7-1) and DNA Match Confirmation Letters. Personnel who are undergoing training are appropriately supervised.

5.2.1.1 Each unit within the FBI Laboratory has a documented training program including a training manual(s) that is used to develop an individual's knowledge, skills, and abilities required to perform forensic examinations and DNA databasing. The training program also requires presentations by trainees to occur at specific intervals. Additionally, these training programs provide for maintaining the skills and expertise of unit personnel and provide for retraining, when needed. When hiring an experienced examiner/technician, the Unit Chief or Technical Leader is responsible for assessing his/her previous training and ensuring it is adequate and documented. Modification to the training program may be appropriate and will be documented by the Unit Chief or Technical Leader. Each Unit Chief or Technical Leader ensures that, at a minimum, a trainee successfully completes a competency test according to QAM – Section (5.2.6.2.2) in the relevant discipline(s) and/or category(ies) of testing prior to conducting independent casework or DNA databasing. A trainee's successful completion of the training program is documented in an EC generated by the Unit Chief or designee identifying the discipline(s) and/or category(ies) of testing, associated equipment, and his/her position (examiner or technician).

5.2.1.2 Prior to qualification, FBI Laboratory examiner trainees, as defined by the unit, undergo moot court training in their respective discipline(s) and/or category(ies) of testing according to the LOM – Practices for Moot Court and Admissibility Hearing Exercises. Unit Chiefs ensure moot court training is included in unit training programs where testifying is an expected job duty.

5.2.1.3 Unit training programs also include ethical practices in forensic sciences, a general knowledge of forensic science, and applicable criminal and civil law and procedures. These topics are covered in the LOM – Practices for New Employee Training Program.

5.2.2 Technical management establishes objectives for the continuing education of all FBI personnel to meet the present and anticipated needs of the FBI Laboratory. These objectives also satisfy the requirements for the FBI policy on continuing education of personnel. Units have procedures for identifying training needs, providing this training to personnel, and evaluating the effectiveness of this training. Units may specify the types of training (e.g., specific to an employee's daily duties, technical in nature, incurs cost to unit) that require evaluation of effectiveness.

5.2.3 The FBI Laboratory uses qualified technical personnel who are employed by, or under contract to, the FBI. Technical management ensures that contractors are supervised and that they work in accordance with the FBI Laboratory's quality system.

5.2.4 Current job descriptions for all FBI Laboratory personnel are maintained in the Administrative Unit.

5.2.5 FBI Laboratory management authorizes qualified personnel to perform forensic examinations or DNA databasing with associated equipment. Each unit maintains records of an employee's qualifications to include education, professional experience, competency test results, proficiency test results, and an EC documenting successful completion of the training program according to QAM – Section (5.2.1.1). Units may have additional authorization records. The above requirements also apply to contractors. These records are available in the appropriate unit.

5.2.6 Examiner/Technician Qualifications

5.2.6.1 Education

5.2.6.1.1 Examiners working in the Drug Chemistry and Trace Evidence disciplines of forensic science possess a baccalaureate or an advanced degree in a natural science or a closely related field.

5.2.6.1.2 Examiners working in the Toxicology discipline of forensic science possess a baccalaureate or an advanced degree in a natural science, toxicology, or a closely related field.

5.2.6.1.3 Examiners working in the Biology discipline of forensic science possess a baccalaureate or an advanced degree in a natural science or a closely related field and, if performing DNA analysis and where applicable, meet the educational requirements of the Quality

Assurance Standards for Forensic DNA Testing Laboratories or Quality Assurance Standards for DNA Databasing Laboratories, as appropriate.

5.2.6.1.4 Examiners working in the Latent Prints, Firearms/Toolmarks, Questioned Documents, Crime Scene, and Cryptanalysis and Racketeering Records disciplines of forensic science meet the educational requirement(s) specified in the job description.

5.2.6.1.5 FBI Laboratory technicians meet the educational requirement(s) specified in the job description.

5.2.6.2 Competency Testing

5.2.6.2.1 All examiners and technicians satisfactorily complete a competency test in each category of testing prior to assuming casework or DNA database responsibilities or crime scene duties in the FBI Laboratory.

5.2.6.2.2 For FBI Laboratory staff whose responsibility includes writing *Reports of Examination* (7-1), his/her competency test includes, at a minimum:

- Examination of sufficient unknown samples to cover the anticipated spectrum of job duties and evaluate his/her ability to perform suitable testing methods;
- A written 7-1 to demonstrate his/her ability to appropriately convey results and/or conclusions and their significance;
- A written or oral examination to assess his/her knowledge of the discipline, category of testing, or task being performed.

5.2.7 The FBI Laboratory maintains a library that provides access to forensic science resources such as relevant books, journals, and literature.

5.3 Facilities and Environmental Conditions

5.3.1 FBI Laboratory facilities permit the correct performance of forensic examinations and DNA databasing. Units ensure that the environmental conditions do not adversely affect the quality required of any measurement. Any environmental conditions that can affect the results of examinations/DNA databasing are documented in the appropriate standard operating procedure. All examinations/DNA databasing require normal laboratory environmental conditions unless noted in a standard operating procedure. Extreme care is taken when sampling and/or examinations are undertaken at sites other than a permanent FBI Laboratory facility.

5.3.2 If environmental conditions affect the quality of an examination/DNA databasing, the affected units will monitor, control, and record those conditions as required by a standard operating procedure. Examinations/DNA databasing are stopped when the environmental conditions jeopardize the results.

5.3.3 FBI Laboratory units are responsible for maintaining effective separation between incompatible activities to prevent cross-contamination. [LOM - Practices for the Examination of Evidence]

5.3.4 Access to and use of all laboratory areas is controlled and limited.

5.3.4.1 FBI Laboratory policies and/or practices for security are found in the LOM - Practices for the Security of Evidence Storage Rooms, the Security Reference Guide for Laboratory Division Personnel, and the Security Policy Manual. The FBI Laboratory Chief Security Officer is responsible for ensuring that the FBI Police and/or other FBI Laboratory security personnel are familiar with FBI Laboratory security policies and practices. These policies and practices ensure that:

- Visitors do not have unrestricted access to the operational areas of the FBI Laboratory.
- All exterior entrance/exit points have proximity badge readers and closed circuit television monitoring to enforce security and the entire outer perimeter of the FBI Laboratory has security control at all times.
- Internal areas requiring limited/controlled access have a lock system.
- All access keys and Security Access Control (SACS) badges are accounted for by the FBI Laboratory Chief Security Officer and their distribution limited to those individuals approved by the FBI Laboratory Director.
- The FBI Laboratory is monitored during vacant hours by an intrusion alarm, FBI Police, and/or other FBI Laboratory security personnel.
- Evidence storage areas are secured using intrusion detection and lock systems. The storage conditions are such as to prevent loss, deterioration, and contamination as well as to maintain the integrity of the evidence. This applies both before and after examinations have been performed.

5.3.5 The FBI Laboratory Safety Manual requires good housekeeping in the FBI Laboratory. Units create special housekeeping procedures when necessary to ensure the quality of examinations/DNA databasing.

5.3.6 The FBI Laboratory Safety Manual documents the FBI Laboratory's Health and Safety Program.

5.4 Examination/DNA Databasing Procedures and Procedure Validation

5.4.1 General

Standard operating procedures (SOPs), including validated technical procedures, are a key element in establishing and maintaining quality within the FBI Laboratory. Thus, it is the policy of the FBI Laboratory for units to have and use written procedures for all examinations/DNA databasing within their scope. [LOM - Practices for the Examination of Evidence] These procedures include, when necessary, handling, transfer, storage, and preparation of evidence/DNA database samples to be examined. SOPs have a section for the estimation of the measurement uncertainty; a section on

sampling; a section on calculations, including any statistical techniques for the analysis of examination/DNA database data; and a section on limitations of the procedure including any quality affecting environmental conditions. All SOPs used in the FBI Laboratory are reviewed and authorized prior to implementation according to the LOM - Practices for Document Control.

Units have procedures and/or instrumentation manuals for operating all FBI Laboratory equipment and for handling and preparing evidence for examination and DNA database samples to ensure the quality of the results. Any deviations from an SOP are documented, justified, and authorized according to the LOM - Practice for Authorizing Deviations.

5.4.2 Selection of Technical Procedures

Examiners select appropriate technical procedures to meet the needs of the contributor while taking into account the nature of the evidence and the facts of the case. These technical procedures are published either in international, regional or national standards, or by reputable technical organizations, in relevant scientific texts or journals, as specified by the manufacturer of the equipment, or developed by the FBI Laboratory. If the FBI Laboratory uses a standard procedure, it uses the latest edition when possible. The standard procedure is supplemented with additional details to ensure consistent application. The FBI Laboratory confirms that it can properly use a standard procedure prior to introducing it for forensic examinations. If the standard procedure changes, the confirmation will be repeated. FBI Laboratory-developed technical procedures or procedures adopted by the FBI Laboratory, including standard procedures, are used as appropriate.

5.4.3 FBI Laboratory-Developed Technical Procedures

When a unit develops a technical procedure, it will be a planned activity that is performed by qualified personnel with adequate resources. Any significant changes occurring during the development of the procedure are effectively communicated to all personnel involved in the development process. [LOM - Practices for Developing Technical Procedures and LOM - Practices for Validating Chemical Procedures]

5.4.4 Deviation from Technical Procedures

Units use validated technical procedures; however, this does not prevent the examiner from deviating from a procedure if the nature of the evidence or DNA database sample precludes the use of a standard operating procedure. Changes to or deviations from a technical procedure must be within the bounds of good laboratory practice, documented, justified, and authorized according to the LOM - Practice for Authorizing Deviations.

5.4.5 Validation of Technical Procedures

5.4.5.1 Appropriate validation studies are conducted on all new technical procedures used for the analysis of evidence.

5.4.5.2 Validations for new technical procedures are performed according to the LOM - Practices for Validating Technical Procedures and/or LOM - Practices for Validating Chemical Procedures, as appropriate, to ensure the procedure produces reliable results. The validation process determines the limitations of the procedure, the conditions under which reliable results can be obtained, and the critical aspects of the procedure that must be carefully controlled and monitored. Units maintain records of the validation including, the procedure used, the results, and a statement as to whether the technical procedure is fit for its intended use.

5.4.5.3 When validating a technical procedure, the scope and accuracy will be assessed to ensure that the procedure meets the requirements of a given application.

5.4.5.4 The reliability of a validated technical procedure that is new to the FBI Laboratory is confirmed in-house against any documented performance characteristics of that procedure prior to first use. Records of performance verification conducted during the validation process are maintained in the units for future reference.

5.4.6 Estimation of Uncertainty of Measurement

5.4.6.1 The FBI Laboratory does not perform calibration services and thus does not have a procedure for estimating measurement uncertainty for calibrations.

5.4.6.2 Standard operating procedures, when applicable, include considerations for estimating the uncertainty of measurement. If the nature of the examination procedure precludes a metrologically and statistically valid calculation of uncertainty of measurement, the units attempt to identify all the components of uncertainty and produce a reasonable estimate.

Units identify in each appropriate SOP when uncertainty of measurement may be reported and will follow the ASCLD/LAB Policy on Measurement Uncertainty when determining their uncertainty estimates. Units will estimate the measurement uncertainty for any area of testing where the contributor makes the request or the jurisdiction or statute requires such. At a minimum, the uncertainty of measurement will be assessed when quantitative values are reported for:

- The quantity (mass or volume) of a controlled substance, or the presence of a controlled substance when it is reported as a percentage (mass or volume fraction) of the whole sample;
- The concentration (mass or volume fraction) of a drug in a toxicology sample, including values reported for blood alcohol;
- The barrel length of a firearm and/or the overall length of a firearm.

An FBI Laboratory *Report of Examination* (7-1) must not give a wrong impression of the uncertainty of measurement.

Records are maintained by the units to describe the process used to develop the estimation of uncertainty. Estimates of uncertainty of measurement must be available for review when any of the following conditions exist:

- The measurement uncertainty is relevant to the validity or interpretation of the examination results.
- The measurement uncertainty is required by the contributor.
- The measurement uncertainty affects compliance to a specific limit.

5.4.6.3 Estimation of uncertainty of measurement is based on knowledge of the performance of the method, previous experience, and validation data as well as any significant parameters that affect the measurement result.

5.4.7 Control of Data

5.4.7.1 Units ensure that manual calculations, data transcriptions, and data reductions relevant to examinations are systematically checked for accuracy.

5.4.7.2 When computers or automated equipment are used for forensic examinations or DNA databasing, units ensure that:

- Computer software developed in-house is documented, evaluated, and validated prior to use;
- Procedures for protecting test data maintain the integrity and confidentiality of the data;
- Operating conditions and maintenance are such that computers and automated equipment function properly.

5.4.7.2.1 The FBI Laboratory does not examine digital evidence.

5.5 Equipment

5.5.1 The FBI Laboratory is furnished with, or has access to, all items needed for the correct performance of forensic examinations/DNA databasing. All instruments and equipment having an effect on the accuracy or validity of forensic examination and DNA database results are properly maintained and calibrated. Requirements for instrument calibration and maintenance are specified in the LOM - Practices for Instrument Calibration and Maintenance. In those cases where a unit needs to use equipment outside its permanent control, it ensures that the requirements of ASCLD/LAB-*International* are met.

5.5.2 Equipment and its software used for the examination of evidence or DNA databasing must meet the requirements of the relevant SOP. Before being placed into service, equipment is calibrated and/or checked by the unit to verify that it meets the unit's specifications. As appropriate, units establish calibration programs for equipment having a significant effect on the results. Equipment is also calibrated and/or checked before use in accordance with a particular SOP. [LOM - Practices for Instrument Calibration and Maintenance]

5.5.3 FBI Laboratory equipment is operated by authorized, qualified personnel. [QAM - Section (5.2.5)] Units keep up-to-date instructions for the use and maintenance of equipment. The manufacturer's manuals for equipment are also available to the appropriate personnel.

5.5.4 FBI Laboratory instruments, equipment, and their associated software used for forensic examinations and DNA databasing are uniquely identified. [LOM - Practices for Instrument Calibration and Maintenance]

5.5.5 Units maintain records of each instrument and its associated software used for forensic examinations or DNA databasing according to the LOM - Practices for Instrument Calibration and Maintenance.

5.5.6 Units have procedures for appropriate storage, transportation, use, and planned maintenance of portable equipment to ensure proper functioning. [LOM - Practices for Instrument Calibration and Maintenance]

5.5.7 Any instrumentation that is malfunctioning is taken out of service and clearly labeled to prevent use until repairs are completed. Only when it is shown by calibration or a performance check to operate correctly will the instrument be returned to service. [LOM - Practices for Instrument Calibration and Maintenance] Units determine the effect of the malfunction, if any, on test results and implement "Control of Nonconforming Testing" in QAM - Section (4.9), when necessary.

5.5.8 FBI Laboratory instrumentation requiring calibration are labeled or otherwise identified to indicate the calibration status, when practicable. [LOM - Practices for Instrument Calibration and Maintenance]

5.5.9 Calibration procedures or performance checks must be satisfactorily completed by the appropriate unit on any instrument that goes outside the control of the FBI Laboratory for testing activities prior to its return to service. [LOM - Practices for Instrument Calibration and Maintenance]

5.5.10 When necessary, performance checks are carried out on calibrated equipment according to the appropriate SOP. [LOM - Practices for Instrument Calibration and Maintenance]

5.5.11 Where instrument calibrations or performance checks produce a set of correction factors, the units have measures to ensure that the correction factors are made available to appropriate personnel.

5.5.12 Units ensure that instrumentation used for forensic examinations or DNA databasing, including both hardware and software, are safeguarded from adjustments which would invalidate the test results.

5.6 Measurement Traceability

5.6.1 General

The FBI Laboratory requires that instrumentation that has a significant effect on the accuracy or validity of the examination or DNA databasing result(s), is calibrated prior to being put into service

for forensic examinations or DNA databasing according to the LOM - Practices for Instrument Calibration and Maintenance.

5.6.1.1 FBI Laboratory units have established calibration or performance check intervals for each instrument requiring calibration. Intervals are generally not longer than the manufacturer's recommendations. However, instruments that are not calibrated or performance checked according to the manufacturer's recommended intervals are calibrated or performance checked prior to use. If an instrument can be affected by a power interruption, unit personnel will check the calibration after a shut down, whether deliberate or otherwise. Instrument calibration is checked following service or other substantial maintenance. [LOM - Practices for Instrument Calibration and Maintenance]

5.6.2 Specific Requirements

5.6.2.1 Calibration

The FBI Laboratory is not a calibration laboratory.

5.6.2.2 Testing

5.6.2.2.1 If it has been established that an instrument's calibration contributes little to the total uncertainty of the test result, units will ensure that the instrument used can provide the necessary uncertainty of measurement. If the calibration is a significant component of the measurement uncertainty, units must establish traceability to the International System of Units (SI units) for the calibration.

Units that perform internal calibrations of instrumentation establish traceability by a means of an unbroken chain of calibrations or comparisons linking the calibration standards to the relevant primary standards of the SI units of measurement.

When necessary, units will utilize competent external calibration services that can demonstrate measurement capability and traceability according to the LOM - Practices for Instrument Calibration and Maintenance.

5.6.2.2.2 Measurements made should be traceable to SI units. The link to SI units may be achieved by reference to national measurement standards.

Where traceability of measurements to SI units is not possible and/or not relevant, units will establish traceability to other appropriate measurement standards such as certified reference materials or reference standards.

5.6.3 Reference Standards and Reference Materials

5.6.3.1 Reference Standards

Units have procedures for the calibration of their reference standards to ensure that the calibrating organization provides traceability to SI Units by a means of an unbroken chain of calibrations or comparisons linking the reference standards to the relevant primary standards of the SI units of measurement. Units only use a reference standard for calibration purposes unless it can be shown that any additional use will not invalidate it. When appropriate, reference standards are calibrated before and after any adjustment.

5.6.3.2 Reference Materials

Reference materials are traceable to SI units or to certified reference materials, where practicable. Internal reference materials are checked to verify their suitability. [LOM - Practices for Instrument Calibration and Maintenance]

5.6.3.2.1 Units utilizing reference collections for comparison or interpretation purposes document, uniquely identify, and properly control such references. These references may include mass spectra, motor vehicle paints or headlamp lenses, drug samples, typewriter print styles, bullets, cartridges, DNA profiles, and frequency databases.

5.6.3.3 Intermediate Checks

Units perform checks on reference, primary, or working standards as well as reference materials to maintain confidence in their calibration status in accordance with the appropriate SOPs.

5.6.3.4 Transport and Storage

To protect the integrity of reference standards and materials, units have procedures for their handling, transport, storage, and use.

5.7 Sampling

Sampling is taking a part of a substance, material, or product to provide for testing of a representative sample of the whole. If sampling is performed, plans will be based on statistical methods when appropriate and will address the factors to be controlled to ensure the validity of the examination results. In certain cases, the sample may not be representative but is determined by availability. When sampling is employed, the FBI Laboratory *Report of Examination* (7-1) will state the results about "the whole" based on testing only a portion. From the start of the examination, there must be a statistically based or reasonable assumption of homogeneity of the whole.

Sample selection is the practice of selecting a sample(s) of the whole based upon training, experience and competence. When sample selection is employed, testing will be carried out on the selected sample(s) and the FBI Laboratory *Report of Examination* (7-1) will be clear that the

results are based only on the portion(s) tested. It should be clear to the contributor that no conclusions are being drawn on the portions not tested. There is also no assumption of homogeneity of the whole.

5.7.1 Each unit, when necessary, has sampling plans and/or sample selection procedures included in the appropriate SOPs. The sampling process addresses the factors to be controlled to ensure the validity of the examination results. Sampling procedures should describe the selection, sampling plan, withdrawal and preparation of a sample or sample(s) from a substance, material or product to conduct the appropriate examinations.

5.7.2 If the contributor or the nature of the evidence requires deviation or exclusion from the sampling procedure(s) described in the appropriate SOP, the deviation will be documented by the examiner according to the LOM - Practices for Authorizing Deviations.

5.7.3 Units, as applicable, document appropriate sampling data and activities relating to the forensic examination process. Records are maintained in the FBI Laboratory file and include the sampling procedure(s) used, the identification of the individual performing the sampling, any relevant environmental conditions, diagrams of the sampling location as necessary and, if relevant, the statistical basis for the sampling procedures.

5.8 Handling of Items of Evidence

5.8.1 The FBI Laboratory maintains practices for the transportation, receipt, handling, protection, storage, retention, and/or disposal of items of evidence. These practices give guidance for protecting the integrity of evidence, protecting the interests of the FBI Laboratory and the interests of the contributor. [LOM - Practices for Recording and Acknowledging Evidence, Practices for Inventorying and Identifying Evidence, Practices for Processing a Request for Examination, Practices for the Examination of Evidence, Practices for Shipping Evidence, Practices for Transferring Evidence, Practices for Handling Drug and Valuable Evidence, and Practices for the Security of Evidence Storage Rooms]

5.8.1.1 The FBI Laboratory uses a *Chain-of-Custody Log* (7-243 and/or 7-243a) (See LOM - Practices for Transferring Evidence) to document all internal transfers of evidence from the time of receipt. This record illustrates that the evidence examined and reported on was that which was submitted to the FBI Laboratory. The 7-243 and/or 7-243a identify each person taking possession of an item of evidence or the location of that item. This log includes:

- A signature, initials, equivalent identification, or secure electronic equivalent, at the time of transfer, of the person/location receiving evidence;
- The date of receipt or transfer;
- The description or unique identifier of the evidence.

[LOM - Practices for Transferring Evidence and Practices for Processing a Request for Examination]

5.8.1.1.1 When evidence is sub-divided in the FBI Laboratory, sub-items are tracked on the 7-243 and/or the 7-243a.

5.8.1.1.2 The FBI Laboratory ensures that evidence that is accepted and stored in the FBI Laboratory is properly sealed.

5.8.2 The FBI Laboratory identifies items of evidence according to the LOM - Practices for Inventorying and Identifying Evidence and Practices for the Examination of Evidence. The identification of evidence remains in place while the items are in the FBI Laboratory. These practices ensure that items of evidence are uniquely identified and provide for subdivided and secondary evidence. Evidentiary items are transferred within and from the FBI Laboratory according to the LOM - Practices for Transferring Evidence.

5.8.3 Upon receipt of the evidence, the condition of the evidence is evaluated and any conditions adverse to quality are recorded as described in the LOM - Practices for Inventorying and Identifying Evidence. When the suitability of an item of evidence for examination is questionable, or there is a discrepancy between the evidence and the request for examination, or the request for examination is unclear, the RC or examiner having custody of the evidence will contact the contributor for clarification prior to proceeding with any testing. This communication will be recorded in an *Activity and Communication Log* (7-245) according to the LOM - Practices for Inventorying and Identifying Evidence and Practices for the Examination of Evidence.

5.8.4 The FBI Laboratory ensures the integrity of evidence by protecting items from loss, cross-transfer, or deleterious change during storage, handling, and preparation according to the LOM - Practices for Inventorying and Identifying Evidence, the Practices for the Examination of Evidence, and the Practices for the Security of Evidence Storage Rooms. Appropriate handling instructions provided with an item are followed. When evidentiary items have to be stored or handled under specified environmental conditions, these conditions will be maintained, monitored, and recorded. The LOM - Practices for the Handling of Drug and Valuable Evidence describes how drug and valuable evidence are stored and handled.

5.8.4.1 All evidence not in the process of examination is maintained in a secured, limited-access storage area under proper seal. [LOM - Practices for the Examination of Evidence]

5.8.4.2 The LOM - Practices for the Examination of Evidence describes the measures taken to secure unattended evidence which is in the process of being examined.

5.8.4.2.1 Unit quality manuals have a policy that defines active examination for all evidence in the process of examination. The time period for active examination cannot be open-ended and is based upon a justifiable expectation of frequent examination.

5.8.4.3 Each item of evidence is marked to ensure that it is uniquely identified and traceable to the FBI Laboratory number. If the evidence does not lend itself to marking, its proximal container or identifying tag will be marked. [LOM - Practices for Inventorying and Identifying Evidence and Practices for the Examination of Evidence]

5.8.4.4 When evidence, such as latent prints and impressions, can only be recorded or collected by photography or digital capture and the print or impression itself is not recoverable, the photograph, negative or digital image of the print or impression will be treated as evidence. **5.8.4.5** Evidence collected by FBI Laboratory personnel from a crime scene is protected from loss, cross-transfer, contamination, and/or deleterious change whether in a sealed or unsealed container during transportation to the FBI Laboratory or other appropriate evidence facility. Where relevant, further processing to preserve, evaluate, document, or render evidence safe will be accomplished prior to final packaging. Additionally, crime scene evidence is properly identified, packaged, and entered into the FBI Laboratory evidence control system as soon as possible.

5.8.4.6 Appropriate units have procedures for the operation of individual characteristic databases (ICD).

5.8.4.6.1 Appropriate units have established whether individual characteristic database samples are treated as evidence, reference materials, or examination records.

a) ICD samples treated as evidence are tracked and handled the same as other evidence received in the FBI Laboratory. [LOM - Practices for Recording and Acknowledging Evidence, Practices for Inventorying and Identifying Evidence, Practices for Processing a Request for Examination, Practices for the Examination of Evidence, Practices for Shipping Evidence, Practices for Transferring Evidence, Practices for Handling Drug and Valuable Evidence, and Practices for the Security of Evidence Storage Rooms]
b) ICD samples not treated as evidence meet the requirements in QAM – Section (5.8.4.6.2 through 5.8.4.6.4).

5.8.4.6.2 Each individual characteristic database sample under the control of the applicable units in the FBI Laboratory is uniquely identified.

5.8.4.6.3 Individual characteristic database samples under the control of the applicable units in the FBI Laboratory are protected from loss, cross transfer, contamination, and deleterious change. ICD samples are treated in a manner that reasonably ensures their utility as comparison materials.

5.8.4.6.4 Access to ICD samples under the control of the applicable units in the FBI Laboratory are restricted to those persons authorized by the FBI LaboratoryAD.

5.9 Assuring the Quality of Test Results

5.9.1 FBI Laboratory units have quality control procedures for monitoring the reliability of forensic examinations and DNA databasing. The resulting data is recorded in such a way that trends are detectable and, where practicable, statistical techniques are applied to the reviewing of the results. Quality control measures may include, the following:

- Routine use of certified reference materials and/or secondary reference materials;
- Participation in proficiency testing programs;

- Replication of tests using the same or different methods;
- Retesting of retained items;
- Correlation of results for different characteristics of an item of evidence.

5.9.1.1 Appropriate controls and standards are specified in SOPs and their use recorded in case records or DNA databasing records.

5.9.2 FBI Laboratory units have procedures for evaluating quality control data against defined criteria. When necessary, units will address the problem and take appropriate actions to prevent incorrect results from being reported.

5.9.3 Proficiency testing is an integral part of the FBI Laboratory quality system. It is one of many quality control measures used to monitor the FBI Laboratory's own performance as well as identify areas where improvement may be needed. The FBI Laboratory proficiency testing program is documented in the LOM - Practices for Open Proficiency Testing. In addition, each unit quality manual contains procedures, as appropriate, for both internal and external proficiency testing. Proficiency testing applies to examiners and technicians in each discipline/category of testing in which casework or DNA databasing is performed.

5.9.3.1 Units follow the appropriate SOP(s) when participating in proficiency testing programs. [LOM - Practices for Open Proficiency Testing]

5.9.3.2 The FBI Laboratory proficiency testing program complies with the ASCLD/LAB Proficiency Review Program. [LOM - Practices for Open Proficiency Testing]

5.9.3.3 Each examiner and technician engaged in testing activities successfully completes at least one internal or external proficiency test per calendar year in his/her forensic science discipline(s). [LOM - Practices for Open Proficiency Testing]

5.9.3.3.1 DNA examiners and technicians performing DNA analysis comply with the proficiency test requirements of the Quality Assurance Standards for Forensic DNA Testing Laboratories or Quality Assurance Standards for DNA Databasing Laboratories, as appropriate. [LOM - Practices for Open Proficiency Testing]

5.9.3.3.2 Each examiner and technician engaged in testing activities in ASCLD/LAB-*International* accredited forensic science disciplines successfully completes at least one proficiency test annually in each category of testing appearing on the FBI Laboratory's Scope of Accreditation in which the individual performs testing. A schedule for proficiency testing for each examiner and technician is documented according to LOM - Practices for Open Proficiency Testing.

5.9.3.4 The FBI Laboratory participates annually in at least one external proficiency test for each ASCLD/LAB-*International* accredited forensic science discipline in which it provides services according to the [LOM - Practices for Open Proficiency Testing] ASCLD/LAB approved proficiency test providers are used where available. If there is not an ASCLD/LAB approved test

provider available, the FBI Laboratory locates and uses a source of an external test in the discipline.

5.9.3.5 The FBI Laboratory maintains proficiency testing records according to the LOM - Practices for Open Proficiency Testing.

5.9.3.6 Proficiency testing records are retained permanently according to the LOM - Practices for Open Proficiency Testing.

5.9.4 Technical reviews of examination records and *Reports of Examination* (7-1) are conducted according to the subsections below as well as the LOM - Practices for Reviewing a Report of Examination. Unit quality manuals may contain additional procedures for conducting and documenting technical reviews.

5.9.4.1 A technical review includes a review of all examination records and the *Report of Examination* (7-1) to ensure at a minimum:

- Conformance with appropriate technical procedures and applicable portions of the QAM, LOM, unit quality manuals, and SOPs;
- Accuracy of the 7-1 and that the data supports the results and/or conclusions of the 7-1;
- Associations are appropriately qualified in the 7-1;
- The 7-1 contains all the required information.

5.9.4.2 Technical reviews are conducted by individuals who are qualified in the category of testing being reviewed. Additionally, the technical reviewer has knowledge of the SOPs used in that category of testing.

5.9.4.3 Technical reviews are not conducted by the examiner or co-examiner(s) who authored the examination records or the *Report of Examination* (7-1) under review.

5.9.5 A Unit Chief or designee conducts an administrative review on all unit records in the FBI Laboratory file as well as the FBI Laboratory *Report of Examination* (7-1) prior to its release according to the subsection below as well as the LOM - Practices for Reviewing a Report of Examination. Administrative reviews are not conducted by the examiner or co-examiner(s) who authored the *Report of Examination* (7-1) under review. Unit quality manuals may contain additional procedures for conducting and documenting administrative reviews.

5.9.5.1 An administrative review includes a review of all administrative and examination records and the *Report of Examination* (7-1) to ensure at a minimum:

- Spelling and grammatical accuracy;
- Administrative and examination records are uniquely identified according to the LOM - Practices for the Examination of Evidence;
- Key information is present in the 7-1.

5.9.6 The FBI Laboratory follows the LOM - Practices for Court Testimony Monitoring whereby the testimony of all testifying personnel is monitored and evaluated. Each individual is given feedback, both positive and in any area needing improvement, by his/her Unit Chief or designee. If the evaluation is unsatisfactory, the Unit Chief will initiate remedial action(s) according to the LOM - Practices for Court Testimony Monitoring.

5.9.7 Records of testimony monitoring are retainedaccording to the LOM - Practices for Court Testimony Monitoring.

5.10 Reporting the Results

5.10.1 General

FBI Laboratory personnel accurately, clearly, unambiguously, and objectively report the results of each examination according to the LOM - Practices for the Formatting and Content of a Report of Examination and unit quality manuals and/or SOPs. FBI Laboratory *Reports of Examination* (7-1) include information regarding the examinations conducted and any information necessary for the interpretation of the examination results.

5.10.1.1 The FBI Laboratory generates an FBI Laboratory *Report of Examination* (7-1) for every request for examination. For examinations that are canceled or discontinued, the FBI Laboratory *Report of Examination* (7-1) is prepared according to the LOM - Practices for the Examination of Evidence.

5.10.2 Content of *Reports of Examination*

The LOM - Practices for the Formatting and Content of a Report of Examination and unit quality manuals and/or SOPs provide guidance for the content of an FBI Laboratory *Report of Examination* (7-1).

5.10.3 Additional *Report of Examination* Guidelines

5.10.3.1 An FBI Laboratory *Report of Examination* (7-1) may include additional information, such as deviations from the test method, information on test conditions, statement on the uncertainty of measurement, or additional information which may be required by specific methods or contributors, when it is necessary for the interpretation of the examination results according to the LOM - Practices for the Formatting and Content of a Report of Examination.

5.10.3.2 An FBI Laboratory *Report of Examination* (7-1) may include additional information regarding sampling including deviations from sampling plan, when it is necessary for the interpretation of the examination results according to the LOM - Practices for the Formatting and Content of a Report of Examination.

5.10.3.3 FBI Laboratory *Reports of Examination* (7-1) are issued according to the LOM - Practices for Issuing a Report of Examination.

5.10.3.4 Examiners who issue findings, including writing *Reports of Examination* (7-1) and providing testimony, based on examination records generated by another person, document the review of examination records according to the LOM - Practices for the Examination of Evidence.

5.10.3.5 The significance of an association is included in the FBI Laboratory *Report of Examination* (7-1).

5.10.3.6 Comparative examinations that result in an elimination are clearly stated in the FBI Laboratory *Report of Examination* (7-1).

5.10.3.7 When a definitive conclusion cannot be reached, the reason is clearly stated in the FBI Laboratory *Report of Examination* (7-1).

5.10.4 Calibration Certificates

The FBI Laboratory does not issue calibration certificates.

5.10.5 Opinions and Interpretations

Opinions and interpretations are identified in FBI Laboratory *Reports of Examination* (7-1) according to the LOM - Practices for Formatting and Content of a Report of Examination. The examiner documents the basis for his/her opinions and/or interpretations in the examination records.

5.10.6 Testing Results Obtained from Subcontractors

When an FBI Laboratory *Report of Examination* (7-1) contains results of tests performed by an expert outside the FBI Laboratory, those results will be clearly identified. If the examination results are not included in the 7-1, the Unit Chief or designee will ensure that the contributor receives a copy of the expert's report.

5.10.7 Electronic Transmission of Results

ASCLD/LAB- *International* requirements apply to the transmission of FBI Laboratory *Reports of Examination* (7-1) and examination results by telephone, facsimile, or other electronic or electromagnetic means.

5.10.8 Format of *Report of Examination*

An FBI Laboratory *Report of Examination* (7-1) is formatted according to the LOM - Practices for Formatting and Content of a Report of Examination.

5.10.9 Amendments to *Reports of Examination*

Once an FBI Laboratory *Report of Examination* (7-1) has been issued, any amendments or supplements are made in the form of another 7-1 according to the LOM - Practices for Formatting

and Content of a Report of Examination. An amended or supplemental *Report of Examination* (7-1) meets all requirements of QAM - Section (5.10.1, 5.10.2, 5.10.3). A supplemental or amended 7-1 is uniquely identified and contains a reference to the original 7-1 it is replacing.

6 References

ASCLD/LAB-*International* Supplemental Requirements for the Accreditation of Forensic Science Testing Laboratories, American Society of Crime Laboratory Directors/Laboratory Accreditation Board, Garner, NC, 2011.

Code of Federal Regulations, Title 28, Section 0.85.

FBI Laboratory Operations Manual, Federal Bureau of Investigation, Laboratory Division, latest revision.

FBI Laboratory Safety Manual, Federal Bureau of Investigation, Laboratory Division, latest revision.

Field Evidence Management and Operations Policy Implementation Guide, Federal Bureau of Investigation, October 27, 2009.

Handbook of Forensic Services, Federal Bureau of Investigation, Laboratory Division, latest revision.

International Vocabulary of Basic and General Terms in Metrology, International Organization for Standardization, Geneva, Switzerland, 1993.

ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories, International Organization for Standardization, Geneva, Switzerland, 2005.

Manual of Administrative Operations and Procedures, Federal Bureau of Investigation, 2006.

Marking Guide, US National Archives and Records Administration, Information Security Oversight Office, October 2003.

Metric System of Measurement: Interpretation of the International System of Units for the United States, National Institute of Standards and Technology, Federal Register, Vol. 63, No. 144, Notices, July 28, 1998.

Quality Assurance Standards for Forensic DNA Testing Laboratories, Federal Bureau of Investigation, September 1, 2011.

Quality Assurance Standards for DNA Databasing Laboratories, Federal Bureau of Investigation, September 1, 2011.

Security Policy Manual, Federal Bureau of Investigation, Security Division, latest revision.

Security Reference Guide for Laboratory Division Personnel, Federal Bureau of Investigation, Laboratory Division, latest revision.

United States Code, Title 28, Section 533.

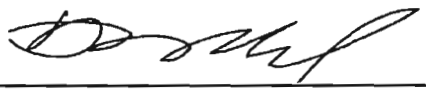
Corporate Policy Directives, FBI, latest revision.

Rev. #	Issue Date	History
5	12/07/11	Updated definitions of auditor, competency test, crime scene personnel, deviation, document, examiner, open proficiency test, technical management, and technician. Added definitions related to DNA databasing and added unit technical management. Added forms and DNA database and associated information throughout entire document as appropriate. Removed caseworking and examination references as appropriate throughout the document. Added sections 3.5.1 and 3.5.2 to include information from the ASCLD/LAB-*International* Program Overview. Removed Casework from title of LOM Conflict Practice in section 3.6.1. Modified sections 3.7.1 and 5.3.4 to clarify laboratory areas. Revised section 4.1.8 from executive to top management in regards to designating key management. Reworded section 4.2.5 and added Technical Leader. Clarified role of Technical Leader in section 4.2.6.3. Removed required identification information from section 4.3.2.3 as and deleted change indicator information from section 4.3.3.1 as it is covered in LOM – Practices for Document Control. In section 4.3.3.2, clarified what documents are required to have new or altered text identified. Added Technical Leader to section 4.5.1. Replaced Quality Manager with Technical Management in section 4.8. For section 4.11.1, added statement about integrity of evidence for consistency with corrective action definition. Updated 4.15.2 to more accurately reflect ISO 17025 requirement. Added Technical Leader to duties in section 5.2.1.1. Updated section 5.2.6.2.1 to include technicians. Updated section 5.4.6.2 to include information from the ASCLD/LAB-*International* Policy on Measurement Uncertainty. Clarified section 5.7 for consistency with ASCLD/LAB. Removed reference to deleted portion of QAM in section 5.10.1. Removed information in section 5.10.3 concerning outside entities providing reports to caseworking units for subcontracted or facilitated forensic examinations. Updated references.
6	09/10/12	Deleted definitions and refer to LOM in section 2. Deleted sections 3.2, 3.4, and 3.6 as these are covered in other documents in the quality system or FBI policy and renumbered section 3. Replaced MAOP references with Corporate Policy Directives where appropriate in section 4.1.5b. Added links to LOM – Case Assignment in reference to 7-262 in section 4.4.1, LOM – Examination of Evidence in reference to 7-245 in section 4.4.2, and LOM – Transferring Evidence in reference to 7-243 in section 5.8.1.1. Updated section 4.13.1.4 to replace ACS and Trilogy. Updated section 4.13.2.1 for consistency with ISO 17025. Clarified section 5.2.2 to provide guidance to units that they may specify what

		training requires evaluation of effectiveness. Added reference to LOM – Practices for Validating Chemical Procedures to section 5.4.5.2. Changed "and" to "or" and added "as appropriate" in sections 5.2.6.1.3 and 5.9.3.3.1.
7	03/13/13	Section 1 removed calibration when referring to ASCLD/LAB Supplemental requirements. Section 3.3.2 revised wording regarding on-site to surveillance visit. For section 3.4, clarified authorization responsibility from AD to Security Group. Throughout document, updated initialisms/acronyms (i.e., AD, QATU), use of policies, practices, and procedures (i.e., QAM, LOM), added system when referring to quality as appropriate. Section 4.1.4 revised to and/or when referring to who will be informed of undue pressure and adverse affects to work. In section 4.1.5i changed executive management to AD and/or designee when referring to who Quality Manager has direct access. Changed executive management to top management and added QAWG meetings to section 4.1.6. For section 4.1.7, clarified position name. Refer reader to LOM Definitions in section 4.1.8. Added training manuals when referring to documents FBI committed to and that those manuals are available on intranet in section 4.2.1. Removed statement in section 4.2.2.1 regarding annual review and signing of ASCLD/LAB Guiding Principles. Removed requirement in section 4.2.2.2 for annual review of Guiding Principles to be completed during performance review and provided it as an optional time for this to be completed. Section 4.2.3 rearranged wording and added QAWG meetings. Also added QAWG meetings to section 4.2.4. Section 4.2.5 clarified individual(s) in units issue unit documents. Updated Figure 1. Section 4.2.6.3 changed approval to ensure approval for selection and use of technical procedures. For section 4.2.6.7, added members to title and added bullets for attending QAWG meetings and participating in discussions. Added training manuals on intranet to section 4.3.1. Added reference to QAM 3.3.2 in section 4.9.1. Added FBI policy regarding retention times in section 4.13.1.2 and regarding access to files in section 4.13.1.3. Added other controlled media to section 4.13.1.4. Added reference to QAM 4.13.1.2 to section 4.13.2.1. Clarified options for where instrumental analyses operating parameters are recorded by adding and/or. Clarified major deviation required in section 4.13.2.12. In section 4.14.1, refer reader LOM Definitions for requirements of trained auditor. Changed QATU to Audit Program Manager in section 4.14.1.2. Clarified accreditation anniversary in section 4.15.1. Corrected title of Health and Safety Manual in section 5.1.3.1. Clarified training programs documented in training manuals and that trainees must give presentations in section 5.2.1.1. Added New Employee

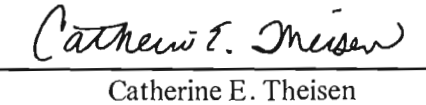
Training program to section 5.2.1.3. For section 5.2.5, clarified requirements for documenting successful completion of training by referring reader to QAM 5.2.1.1 and stated that units may have additional authorization records. Reorganized listing of disciplines in section 5.2.6.1.4. Added and/or instrumentation manuals to section 5.4.1 regarding operating equipment. Added LOM – Practices for Validating Chemical Procedures to section 5.4.3. Clarified appropriate SOP regarding uncertainty of measurement in section 5.4.6.2. Updated reference to QAM in section 5.5.3. Changed can to will in section 5.6.2.2.1 for using competent calibration services. Deleted duplicate sentence about homogeneity in section 5.7. Refer reader to LOM – Practices for Authorizing Deviations in section 5.7.2. Removed reference to LOM – Practices for Inventorying and Identifying Evidence in section 5.8.4.4. Added administrative records are required to be reviewed during administrative review and clarified administrative and examination records are uniquely identified in section 5.9.5.1. Changed may to will regarding initiating remedial action(s) in section 5.9.6. Refer reader to LOM – Practices for Court Testimony Monitoring in section 5.9.7. Added unit quality manuals and SOPs for reporting requirements in sections 5.10.1 and 5.10.2. Removed reference to QAM 3.4 and 5.4.7 from section 5.10.7. Updated references in section 6.

Approval

Laboratory Director  Date: 03/09/2013

D. Christian Hassell

Approval/Issuance

Quality Manager  Date: 03/09/2013

Catherine E. Theisen

Appendix A: *ASCLD/LAB GUIDING PRINCIPLES OF PROFESSIONAL RESPONSIBILITY FOR CRIME LABORATORIES AND FORENSIC SCIENTISTS*

ASCLD/LAB GUIDING PRINCIPLES OF PROFESSIONAL RESPONSIBILITY FOR CRIME LABORATORIES AND FORENSIC SCIENTISTS

"If the law has made you a witness,
Remain a man of science.
You have no victim to avenge,
No guilty or innocent person to convict or save --
You must bear testimony within the limits of science."

Dr. P.C.H. Brouardel
19th Century French Medico-legalist

Preamble

These Guiding Principles are written specifically for forensic scientists[i] and laboratory management. The concepts presented here have been drawn from other professional codes and suggestions made by leaders in the forensic community.[ii] The Guiding Principles have been vetted[iii] and adopted by the ASCLD/LAB Board of Directors and staff with the hope that laboratory management will use them in training sessions, performance evaluations, disciplinary decisions, and as guides in other management decisions. It is also important that all laboratory personnel, including forensic scientists and other laboratory employees who assist forensic scientists in their work, are equally aware of these Guiding Principles and support forensic scientists and managers by incorporating the principles into their daily work.

These Guiding Principles provide a framework for describing ethical and professional responsibilities in the forensic laboratory community. While not all inclusive, they describe key areas and provide some specific rules to supplement existing codes of ethics adopted by professional organizations and individual laboratories. The Guiding Principles are designed to promote integrity among practitioners, and to increase public confidence in the quality of laboratory services, whether or not the laboratory is accredited by any accrediting body.

ASCLD/LAB has adopted the ASCLD Guidelines for Forensic Laboratory Management Practices, many of which have been incorporated into the ASCLD/LAB accreditation standards. These practices provide for management support of the guiding principles set forth below and are intended to create a culture of ethical behavior and professional responsibility within the laboratory. The ASCLD practices should be implemented and followed to give practical meaning to the Guiding Principles of Professional Responsibility for Crime Laboratories and Forensic Scientists.

Appendix A: *ASCLD/LAB GUIDING PRINCIPLES* continued

Professionalism

The ethical and professionally responsible forensic scientist and laboratory manager . . .

1. Are independent, impartial, detached, and objective, approaching all examinations with due diligence and an open mind.
2. Conduct full and fair examinations. Conclusions are based on the evidence and reference material relevant to the evidence, not on extraneous information, political pressure, or other outside influences.
3. Are aware of their limitations and only render conclusions that are within their area of expertise and about matters which they have given formal consideration.
4. Honestly communicate with all parties (the investigator, prosecutor, defense, and other expert witnesses) about all information relating to their analyses, when communications are permitted by law and agency practice.
5. Report to the appropriate legal or administrative authorities unethical, illegal, or scientifically questionable conduct of other laboratory employees or managers. Laboratory management will take appropriate action if there is potential for, or there has been, a miscarriage of justice due to circumstances that have come to light, incompetent practice or malpractice.
6. Report conflicts between their ethical/professional responsibilities and applicable agency policy, law, regulation, or other legal authority, and attempt to resolve them.
7. Do not accept or participate in any case on a contingency fee basis or in which they have any other personal or financial conflict of interest or an appearance of such a conflict.

Competency and Proficiency

The ethical and professionally responsible forensic scientist and laboratory manager . . .

8. Are committed to career-long learning in the forensic disciplines which they practice and stay abreast of new equipment and techniques while guarding against the misuse of methods that have not been validated. Conclusions and opinions are based on generally accepted tests and procedures.
9. Are properly trained and determined to be competent through testing prior to undertaking the examination of the evidence.
10. Honestly, fairly and objectively administer and complete regularly scheduled:
    - relevant proficiency tests;

Appendix A: *ASCLD/LAB GUIDING PRINCIPLES* continued

- comprehensive technical reviews of examiners' work;
- verifications of conclusions.

11. Give utmost care to the treatment of any samples or items of potential evidentiary value to avoid tampering, adulteration, loss or unnecessary consumption.
12. Use appropriate controls and standards when conducting examinations and analyses.

Clear Communications

The ethical and professionally responsible forensic scientist and laboratory manager . . .

13. Accurately represent their education, training, experience, and area of expertise.
14. Present accurate and complete data in reports, testimony, publications and oral presentations.
15. Make and retain full, contemporaneous, clear and accurate records of all examinations and tests conducted, and conclusions drawn, in sufficient detail to allow meaningful review and assessment of the conclusions by an independent person competent in the field. Reports are prepared in which facts, opinions and interpretations are clearly distinguishable, and which clearly describe limitations on the methods, interpretations and opinions presented.
16. Do not alter reports or other records, or withhold information from reports for strategic or tactical litigation advantage.
17. Support sound scientific techniques and practices and do not use their positions to pressure an examiner or technician to arrive at conclusions or results that are not supported by data.
18. Testify to results obtained and conclusions reached only when they have confidence that the opinions are based on good scientific principles and methods. Opinions are to be stated so as to be clear in their meaning. Wording should not be such that inferences may be drawn which are not valid, or that slant the opinion to a particular direction.
19. Attempt to qualify their responses while testifying when asked a question with the requirement that a simple "yes" or "no" answer be given, if answering "yes" or "no" would be misleading to the judge or the jury.

Appendix A: *ASCLD/LAB GUIDING PRINCIPLES* continued

[i] The term "forensic scientist" is used throughout this document. These Guiding Principles are meant to apply to all laboratory personnel, including technical support personnel and others who assist forensic scientists in their work.

[ii] The materials from which the concepts embodied in these Guiding Principles have been drawn include:

a. ASCLD Guidelines for Forensic Laboratory Management Practices. http://ascld.org/files/library/labmgtguide.pdf.

b. ASCLD Code of Ethics. http://ascld.org/files/library/Code%20of%20Ethics.pdf

c. American Academy of Forensic Sciences Code of Ethics and Conduct. www.aafs.org.

d. The Code of Ethics of the California Association of Criminalistics. www.cacnews.org.

e. The Code of Ethics of the Midwestern Association of Forensic Scientists, Incorporated. www.mafs.net.

f. Schroeder, O. C., "Ethical and Moral Dilemmas Confronting Forensic Scientists," *Journal of Forensic Sciences*. Vol. 29, No. 4, Oct. 1984, pp. 966-986.

g. Lucas, D. M., "The Ethical Responsibilities of the Forensic Scientist: Exploring the Limits," *Journal of Forensic Sciences*. Vol. 34, No. 3, May 1989, pp. 719-729.

h. Peterson, J. L., Murdock, J.E., "Forensic Science Ethics: Developing an Integrated System of Support and Enforcement," *Journal of Forensic Sciences*. Vol. 34, No.3, May 1989, pp. 749-762.

i. Saks, M. J., "Prevalence and Impact of Ethical Problems in Forensic Science," *Journal of Forensic Sciences*. Vol. 34, No.3, May 1989, pp. 772-793.

j. Starrs, J.E., "The Ethical Obligations of the Forensic Scientist in the Criminal Justice System," *Journal of the Association of Official Analytical Chemists*. Vol. 54, 1971, pp. 906-914.

[iii] The draft of this document was distributed to thirty (30) forensic science organizations and several legal commentators for comment. The comments received were considered and many suggestions incorporated into the final version.